

**IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION**

IN RE: ETHICON, INC. PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	Master File No. 2:12-MD-02327 MDL No. 2327
THIS DOCUMENT RELATES TO ETHICON WAVE 10 CASES	JOSEPH R. GOODWIN U.S. DISTRICT JUDGE

**MEMORANDUM IN SUPPORT OF DEFENDANTS’ MOTION TO
EXCLUDE CERTAIN GENERAL OPINIONS OF DANIEL ELLIOTT, M.D.**

Defendants Ethicon, Inc., Ethicon LLC, and Johnson & Johnson (hereinafter “Ethicon”) submit this brief in support of their motion to exclude certain general opinions of Daniel Elliott, M.D., as it relates to the cases set forth in Exhibit A to Ethicon’s accompanying motion.

Although Ethicon’s brief in this wave of cases is similar to its brief submitted in prior waves, Ethicon draws special attention to a recent article co-written by Dr. Elliott that directly refutes several assertions he makes in his reports. *See* Ex. G, Brian J. Linder & Daniel S. Elliott, *Synthetic Midurethral Slings*, 46 Urol. Clin. N. Am. 17 (2019) (hereinafter “the 2019 Article”). A comparison of Dr. Elliott’s reports with his 2019 Article reveals as follows:

Dr. Elliott’s Expert Reports	Dr. Elliott’s 2019 Article
“The Polypropylene Mesh in the TVT Should Not Be Used in the Pelvic Floor.” Ex. C, TVT Report at 4.	Polypropylene mesh is the “standard of care” for the surgical treatment of SUI and should only be avoided in limited circumstances. Ex. G, 2019 Article at 21-22.
“Ethicon Failed to Conduct Appropriate Studies Related to the TVT.” Ex. C, TVT Report at 37.	“Synthetic midurethral sling placement is the most extensively researched surgical treatment of SUI, with more than 2000 published articles establishing its effectiveness and describing their safety profile.” Ex. G, 2019 Article at 17.
“The carcinogenic properties of polypropylene also should have been disclosed to doctors, and Ethicon should	“In studies to date, the use of type I polypropylene mesh in pelvic surgery has not been associated with an increased risk of cancer

have done follow-up studies relating to Prolene and cancer.” Ex. E, TVT Secur Report at 19.	formation or other systemic disease.” Ex. G, 2019 Article at 19.
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As set forth in greater detail below, the Court should not allow Dr. Elliott to tell the juries in these cases something completely different than what he tells his peers.

INTRODUCTION

Dr. Elliott is a pelvic surgeon and urogynecologist in Minnesota with experience in the surgical treatment of stress urinary incontinence (“SUI”) and pelvic organ prolapse, as well as the removal of sling systems. Ex. B, curriculum vitae. Dr. Elliott intends to provide general opinions about TVT, TVT-O, and TVT Secur (collectively “the TVT Devices”) used to treat SUI, as well as Prolift, which is used to treat pelvic organ prolapse. Ex. C-F, Expert Reports. As set forth below, the Court should preclude Dr. Elliott from testifying about matters that are beyond his expertise, that are unreliable, that are irrelevant, and/or that are otherwise improper.

LEGAL ARGUMENT

Ethicon incorporates by reference the standard of review for *Daubert* motions set forth by the Court in *Huskey v. Ethicon, Inc.*, 29 F. Supp. 3d 691, 701 (S.D.W. Va. 2014).

I. The Court should preclude Dr. Elliott from testifying that the TVT Devices are unsafe for the surgical treatment of SUI.

In his reports, Dr. Elliott states that the mesh used in the TVT Devices “should not be used in the pelvic floor” and that the TVT Devices “should not be implanted in the human body for use in the treatment of SUI.” Ex. C, TVT Report at 4, 13, 27; Ex. D, TVT-O Report at 4, 14, 41; Ex. E, TVT Secur Report at 5, 13. The Court should not allow Dr. Elliott to provide these opinions because they are directly contradicted by his 2019 Article.

When discussing synthetic midurethral slings, Dr. Elliott states in his 2019 Article that “high-quality evidence exists to support excellent short-term outcomes, with increasing evidence

for their long-term efficacy.” Ex. G, 2019 Article at 22. The article notes the joint statement by the Society for Urodynamics, Female Pelvic Medicine, and Reconstructive Surgery and the American Urogynecologic Society declaring that “polypropylene mesh midurethral slings are a standard of care for the surgical treatment of SUI and represent a great advance in the treatment of this condition.” *Id.* at 21; *see also id.* at 17 (noting that “[t]he expansion of midurethral sling placement has likely been secondary to the ability to perform them on an outpatient basis, with limited morbidity, durable efficacy, and in a less invasive manner than other traditional options” and that “more than 2000 published articles establish[] its effectiveness and describe[] their safety profile”).

Dr. Elliott also states in his 2019 Article that “the **ideal** mesh would be large pore (>75 μ m) and monofilament (type I)” —the precise type of Prolene mesh used in the TVT Devices. *Id.* at 19.

In his expert reports in this litigation, however, Dr. Elliott asserts that polypropylene mesh should *never* be used to treat SUI. Ex. C, TVT Report at 4, 13, 27; Ex. D, TVT-O Report at 4, 14, 41; Ex. E, TVT Secur Report at 5, 13. Dr. Elliott has repeated in his deposition testimony that he believes that all synthetic mid-urethral mesh slings are “unsafe” and that “[m]esh should not be placed in the vagina,” period. Ex. H 9/26/15 Dep. 143:11-14, 144:16-18, 285:22. Yet, in stark contrast, Dr. Elliott states in his 2019 Article that such slings should only be avoided in a few limited situations, such as when a patient is “undergoing concomitant urethral diverticulectomy, urethrovaginal fistula repair, or mesh excision and concomitant SUI surgery,” or the patient is at high risk for poor wound healing or is taking high-dose systemic corticosteroids. Ex. G, 2019 Article at 22-23.

The Court should not allow Dr. Elliott to say one thing to his medical peers and say something completely different to a jury. In this litigation, this Court has precluded Plaintiffs' experts from advancing a position that is inconsistent with the position they have taken in the literature and their professional practice. The Court's decision in *Wilkerson v. Boston Scientific Corp.*, 2015 WL 2087048 (S.D.W. Va. May 5, 2015), is directly on point. There, Plaintiffs' pelvic surgeon expert Jerry Blaivas, M.D., claimed in litigation that polypropylene mid-urethral slings are unsafe for surgically treating SUI. *Id.* at *15. In a 2013 article, however, Dr. Blaivas stated that the "[t]he etiology of mesh sling complications is a matter of conjecture." *Id.* Noting that an expert must "employ[] in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field," this Court precluded Dr. Blaivas from testifying that mesh slings are unsafe because he "employed less intellectual rigor in forming this opinion as an expert witness than he employs when writing studies in his field," rendering his opinion unreliable. *Id.* (quoting *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 152 (1999)).

Just as the Court precluded Dr. Blaivas from testifying that polypropylene midurethral mesh slings are unsafe based on his academic article, the Court should preclude Dr. Elliott from providing this same opinion given what he stated in his 2019 Article. Otherwise, Dr. Elliott will be employing in the courtroom a different level of intellectual rigor than Dr. Elliott employs in his professional practice.

II. The Court should not allow Dr. Elliott to speculate about the duties of a medical device manufacturer.

In his reports, Dr. Elliott criticizes Ethicon for allegedly failing to comply with certain duties owed by a medical device manufacturer. Dr. Elliott is not qualified to provide such testimony, and his opinions are unreliable.

A. Research/Testing

Dr. Elliott faults Ethicon for allegedly not performing certain testing and conducting studies. *See, e.g.*, Ex. C, TVT Report at 29, 33-34, 37; Ex. D, TVT-O Report at 30-31, 35-36, 40-41; Ex. E, TVT Secur Report at 25-28, 43; Ex. F, Prolift Report at 13, 53, 55; Ex. G, 9/26/15 Dep. 240:17-19, 259:8-10, 271:9-16, 275:4-9, 303:21-23. As an initial matter, a lack of testing or a flaw in the design process is not, standing alone, a design defect. *See, e.g., Green v. General Motors Corp.*, 310 N.J. Super. 507, 529 (App. Div. 1998) (“[A] product that is not defective and has not been tested at all remains free of a defect”). The “failure to test” claim here should be seen for what it is—a transparent attempt to shift the burden to the *defendant* to prove the absence of the defect when the plaintiff cannot carry her burden to prove the existence of a defect.

In any event, the Court should exclude these opinions, which are of questionable relevance, because Dr. Elliott is not competent to testify about the level of testing that a manufacturer, such as Ethicon, should have performed and because his opinions are contradicted by his 2019 Article.

1. *Dr. Elliott is not qualified to offer these opinions.*

Even if the degree of testing were relevant, there is nothing in Dr. Elliott’s background that would provide him with specialized knowledge about the testing that Ethicon or other medical device manufacturers supposedly should have performed. He has never manufactured or even worked on the design of a medical device, much less had any involvement with FDA clearance of a medical device. Dr. Elliott’s resume does “not include knowledge or even experience in the manner in which corporations and the [medical device] marketplace react, behave or think regarding their non-scientific goals of maintaining a profit-making organization

that is subject to rules, regulations, standards, customs and practices among competitors and influenced by shareholders or public opinion.” *In re Diet Drugs Prods. Liab. Litig.*, 2000 WL 876900, at *9 (E.D. Pa. June 20, 2000).

Because Dr. Elliott has no relevant experience, he is unable to identify a single rule or regulation that would require Ethicon to conduct different testing. Moreover, Dr. Elliott does not identify *any* basis or reason for these opinions, as he must. Instead, his opinion apparently is based purely on unscientific personal belief. When asked about how certain studies/testing should be conducted, Dr. Elliott responded that he did not know. *See, e.g.*, Ex. H, 9/26/15 Dep. 259:17-21 (“The basic unfortunate reality is it – I don’t know if it could be done”).

Further, a fundamental problem with Dr. Elliott’s opinion that Ethicon should have conducted additional testing and studies before marketing the devices is that Dr. Elliott can only speculate about what those results would have shown. Thus, as noted by one court, “imposition of liability for breach of an independent duty to conduct long-term testing, where the causal link to the known harm to plaintiff is the *unknown outcome of testing that was not done*, would be beyond the pale of any California tort doctrine we can identify.” *Valentine v. Baxter Healthcare Corp.*, 68 Cal. App. 4th 1467, 1486 (1999) (emphasis in original).

This Court has consistently precluded other surgeons from testifying about this issue. In its Wave 1 rulings, the Court found that “[t]here is no indication that Dr. [Bruce] Rosenzweig has any experience or knowledge on the appropriate testing a medical device manufacturer should undertake.” *In re: Ethicon, Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, 2016 WL 4500765, at *5 (S.D.W. Va. Aug. 26, 2016); *see also Huskey v. Ethicon, Inc.*, 29 F. Supp.3d 691, 705 (S.D.W. Va. July 8, 2014) (finding that “there is no indication that [plaintiff’s pelvic surgeon expert] has any experience or knowledge on the appropriate testing a medical device manufacturer should

undertake”); *Carlson v. Boston Scientific Corp.*, 2015 WL 1931311, at *15 (S.D.W. Va. Apr. 28, 2015) (finding that because pelvic surgeon “has no demonstrated training in, knowledge about, or experience with the design of clinical trials or the process of testing medical devices, his opinion falls short of Federal Rule of Evidence 702 and cannot be admitted”). Further, the Court has determined that “[w]hether Ethicon studied certain issues, provided information, or provided guidance are all examples of corporate conduct.” *Bellew v. Ethicon, Inc.*, 2014 WL 12685965, at *9 (S.D. W. Va. Nov. 20, 2014).

Recently, another federal district court, on remand from this Court, agreed with this Court’s reasoning and precluded Dr. Bobby Shull from testifying about research and testing, finding that “Plaintiffs have not shown that Dr. Shull is qualified to testify regarding the standard of care for medical device testing,” and that his opinions about the extent of testing “would merely address facts found in corporate documents.” *Walker v. Ethicon, Inc.*, 2017 WL 2992301, at *5 (N.D. Ill. June 22, 2017). *See also In re: Silicone Gel Breasts Implants Prod. Liab. Litig.*, 318 F. Supp. 2d 879, 901-02 (C.D. Cal. Apr. 22, 2004) (finding that a chemist was not qualified to criticize defendants’ alleged lack of testing and noting that “Plaintiff proffers no evidence that [the expert] has any experience developing an implantable medical device for general use or that he has any foundational knowledge about what standard practices exist in the industry in this regard”).

For these reasons, the Court should preclude Dr. Elliott from offering such testimony in these cases. *See also Hovey v. Cook, Inc.*, 2015 WL 1405565, at *11 (S.D. W. Va. Mar. 26, 2015) (noting in *Daubert* ruling that “plaintiff concedes that ‘Dr. Elliott will not testify that defendant had an obligation to study and failed to do so’”).

2. *Dr. Elliott's opinions about the TVT Devices are refuted by his 2019 Article.*

Even if Dr. Elliott were qualified to testify about the level of studies and testing that Ethicon should have performed his criticisms of studies relative to the TVT Devices are unreliable because they are directly refuted by his 2019 Article. In his 2019 Article, Dr. Elliott states that “[s]ynthetic midurethral sling placement is the most extensively researched surgical treatment of SUI, with more than 2000 published studies establishing the effectiveness and describing their safety profile.” Ex. G, 2019 Article at 17. He also references “high-quality evidence” supporting their efficacy, including “multiple randomized trial describing its safety and efficacy, with results out to 5 years.” *Id.* at 27.

Again, Dr. Elliott is attempting to employ in the courtroom completely different opinions than what he has employed in his field. *See Kumho Tire*, 526 U.S. at 152; *Wilkerson*, 2015 WL 2087048, at *15. Accordingly, the Court should exclude these opinions.

B. Adverse Event Reporting

Dr. Elliott also claims that Ethicon “fail[ed] to properly evaluate and act in response to adverse event reports.” Ex. F, Prolift Report at 55. Dr. Elliott’s experience as a urologist does not qualify him to render opinions on adverse event collection and reporting. He has no relevant experience with the FDA or in the medical device industry that would permit him to offer expert testimony regarding the standard of care for collecting and reporting adverse events. *See, e.g., In re Diet Drugs*, MDL No. 1203, 2001 WL 454586, *16 (E.D. Pa. Feb. 1, 2001) (excluding heart surgeon’s opinions regarding adverse event reporting because surgeon had “no experience or expertise in . . . adverse event reporting” and based his opinions on personal belief rather than reliable methodology).

In its Wave 1 ruling, this Court found that “opinions about Ethicon’s compliance with or violation of the FDA’s labeling and adverse event reporting regulations are **EXCLUDED.**” *In re: Ethicon, Inc.*, 2016 WL 4500766, at *5. The Court should do so again here and clarify that all of Dr. Elliott’s adverse event reporting opinions are excluded, regardless of whether they are specific to compliance with FDA regulations. In *Walker, supra*, the Illinois federal district court prevented Dr. Shull from providing similar criticisms of Ethicon’s response to adverse event reports. *Walker*, 2017 WL 2992301, at *6. According to the court, “[s]imilar to the MDL Court excluding Dr. Shull’s opinion regarding product testing or clinical trials in another case based on a lack of experience with such matters, *see Carlson*, 2015 WL 1931311, at *15, the Court excludes Dr. Shull’s opinion regarding the standard of care for adverse event reporting because Plaintiffs have not demonstrated that Dr. Shull has relevant experience to testify as an expert about this matter.” *Id.* The court further “note[d] that Dr. Shull cannot serve as a conduit for corporate information by testifying about the extent of Defendants’ adverse event reporting.” *Id.*

C. Training

In his Prolift and TVT Secur Reports, Dr. Elliott also claims that Ethicon did not provide appropriate training to physicians. Ex. E, TVT Secur Report at 41-43; Ex. F, Prolift Report at 42-46. Dr. Elliott is not qualified to opine about the level of training that a manufacturer is required to provide, and he admitted that he never participated in any Prolift training. Ex. L, Elliott Nov. 15, 2012 Dep. Tr. 113:3-8; Ex. M, Elliott Nov. 16, 2012 Dep. Tr. 387:11-21. Further, these opinions are irrelevant insofar as Dr. Elliott has not claimed that Plaintiffs’ implanting physicians were inadequately trained. *See Cisson*, 948 F. Supp. 2d at 614 (excluding similar opinions about training under similar circumstances). Consistent with the Illinois federal court’s ruling in *Walker, supra*, the Court should determine that any of Dr. Elliott’s opinions

about training should be limited to a discussion of “the risks of implanting mesh and whether Defendants’ product materials raise those risks, but he may not offer testimony about ‘what information should or should not be included in an [Instructions for Use]’ or other similar materials.” *Walker*, 2017 WL 2992301, at *6.

III. The Court should preclude Dr. Elliott from suggesting that polypropylene mesh may cause cancer.

In his reports, Dr. Elliott suggests that polypropylene mesh has carcinogenic qualities and may cause cancer. Ex. D, TVT-O Report at 36; Ex. E, TVT Secur Report. at 19, 40; Ex. F, Prolift Report at 54. The Court should exclude this highly inflammatory opinion because none of the Plaintiffs alleges to have sustained cancer, no expert alleges that any Plaintiff will develop cancer, and Dr. Elliott himself has acknowledged that there is no link between mesh and cancer.

In his 2019 Article, Dr. Elliott states: “In studies to date, the use of type I polypropylene mesh in pelvic surgery has **not** been associated with an increased risk of cancer formation or systematic disease.” Ex. G, 2019 Article, pp. 19-20 (emphasis added). Therefore, it is wholly disingenuous for Dr. Elliott to suggest otherwise to a jury.

Introduction of irrelevant complications — particularly cancer — is misleading and confusing as well as highly prejudicial. *See, e.g., O’Banion v. Owens-Corning Fiberglas Corp.*, 968 F.2d 1011, 1013 (10th Cir. 1992) (“[E]vidence of cancer is so prejudicial that, in the absence of expert medical testimony that a ‘reasonable degree of medical certainty’ exists that the plaintiff will develop cancer, such evidence should be excluded”); *Tyree v. Boston Scientific Corp.*, 54 F. Supp. 3d 501, 553 (S.D. W. Va. 2014) (“[T]he mention of cancer in this case . . . would, at a minimum, offend Rule 702 and confuse the jury on a matter with scant probative value”). Further, introducing this evidence would be a waste of time, particularly given that

Ethicon would need to expend valuable trial time demonstrating that mesh does not in fact cause problems that Plaintiffs did not even experience.

IV. The Court should limit Dr. Elliott's product warning opinions.

Dr. Elliott claims that the devices' instructions for use ("IFUs") are not adequate. *See* Ex. C, TVT Report at 31-37; Ex. D, TVT-O Report at 37-40; Ex. E, TVT Secur Report at 36-41; Ex. F, Prolift Report at 52-57. Ethicon requests that the Court confine Dr. Elliott's testimony on this issue in the same manner that it has confined all other urogynecologists and pelvic surgeons.

Specifically, this Court has found that "[w]hile an expert who is an obstetrician and gynecologist may testify about the specific risk of implanting mesh and whether those risks appeared on the relevant IFU, the same expert must possess additional expertise to offer expert testimony about what information should or should not be included in an IFU." *See, e.g., In re: Ethicon Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, 2016 WL 4582220, at *3 (S.D. W. Va. Sept. 1, 2016) (limiting Dr. Bobby Shull); *In re: Ethicon, Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, 2016 WL 4536885, at *2 (S.D.W. Va. Aug. 30, 2016) (limiting Dr. Michael Margolis) *In re: Ethicon Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, MDL No. 2327, 2016 WL 4500767, at *4 (S.D.W. Va. Aug. 26, 2016) (limiting Dr. Jerry Blaivas).

Dr. Elliott's opinions fall squarely within these holdings. Dr. Elliott opines that the IFUs were inadequate because Ethicon did not include information about certain risks. *See, e.g.,* Ex. C, TVT Report at 31-37. However, Dr. Elliott's curriculum vitae does not identify any additional expertise to render an opinion about the adequacy of Ethicon's IFUs, as the Court has required of other experts in this litigation. Dr. Elliott's qualifications as it relates to this topic are no different than the qualifications of the other urogynecologists whose opinions the Court has limited. Accordingly, Ethicon requests that the Court limit Dr. Elliott from testifying about

whether specific risks appeared in the IFUs and preclude him from testifying about whether other risks “should or should not be included in an IFU.” *In re: Ethicon, Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, 2016 WL 4536885, at *2.

V. The Court should preclude Dr. Elliott from testifying that non-synthetic mesh procedures are a safer alternative.

Dr. Elliott generally takes the position that the Prolene mesh in the TVT Devices and Prolift is unsafe. He opines that autologous slings and Burch colposuspension are safer alternative procedures for the treatment of SUI and that native tissue repair procedures, such as sacrocolpopexy and colporrhaphy, are a safer alternative to Prolift. Ex. C, TVT Report at 8-9; Ex. D, TVT-O Report at 8-9; Ex. E, TVT Secur Report at 9-10; Ex. F, Prolift Report at 6-7, 56. The Court should exclude these opinions which are irrelevant and unreliable.

A. Dr. Elliott’s opinions on this topic are irrelevant.

Any alleged comparative benefits of the traditional approaches to treat SUI and prolapse recommended by Dr. Elliott are not even relevant to Plaintiffs’ design defect claims, because these approaches are not a medical device and do not entail altering the design of the devices. Ethicon challenged these opinions in its Wave 1 briefing, and the Court determined that “[t]he relevance of this expert testimony is better decided on a case-by-case basis,” and therefore, reserved ruling. *In re Ethicon, Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, 2016 WL 4500766, at *4 (S.D.W. Va. Aug. 26, 2016). Since that time, however, the Court has issued several rulings suggesting that this should be revisited. First, the Court has determined that opinions about alternative procedures are not a case-specific issue, but instead, an issue within “the province of a general causation expert—not a specific causation expert.” *Brooks v. Ethicon, Inc.*, No. 2:12-cv-02865, Mem. Op. at 4 (S.D.W. Va. July 12, 2017), Ex. K hereto.

Second, this Court recently precluded one of Plaintiffs' other general causation experts, Dr. Nathan Goodyear, from offering very similar opinions. In *In re: Ethicon, Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, 2017 WL 1264620, at *3 (S.D.W. Va. Mar. 29, 2017), the Court stated:

Ethicon argues that Dr. Goodyear's opinions regarding *alternative procedures* are irrelevant to the question of whether a safer alternative design of a product exists. Ethicon states, "[A] medical device *product* is not defective in design simply because alternative surgical and nonsurgical *procedures* may exist." Defs.' Mem. Supp. Mot. 4. ***I agree with Ethicon that alternative procedures/ surgeries do not inform the issue of whether an alternative design for a product exists.*** Accordingly, Ethicon's Motion on this point is **GRANTED** and Dr. Goodyear's alternative procedures testimony is **EXCLUDED**.

(Emphasis added).

Third, in *Mullins v. Johnson & Johnson*, 2017 WL 711766, at *2 (S.D.W. Va. Feb. 23, 2017), the Court explicitly found that "[e]vidence that a surgical procedure should have been used in place of a device is not an alternative, feasible design in relation to the TVT." The Court reasoned that "other surgeries or procedures do not inform the jury on *how* the TVT's design could have feasibly been made safer to eliminate the risks that caused the plaintiffs' injuries." *Id.* (emphasis in original). The Court further found that the "the plaintiffs must provide evidence of an alternative, feasible design for the *product* at issue," which entails "provid[ing] sufficient evidence to identify a comparable product or design concept, whether the *design features* of the comparable product or the *design concept* existing at the time of the [device's] manufacture" *Id.* at *3 (emphasis in original). See also *Schmidt v. C.R. Bard, Inc.*, 2013 WL 3802804, at *2 (D. Nev. July 22, 2013) ("[N]on-mesh repair is not an alternative design and does not meet Plaintiff's burden to support" a design-defect claim).¹

¹ These rulings are in accord with others. See, e.g., *Linsley v. C.R. Bard, Inc.*, 2000 WL 343358, *3 (E.D. La. Mar. 30, 2000) (holding that while there existed "alternative techniques" for the mesh surgery, such techniques did not prove an "alternative design" for the polypropylene surgical mesh product). They reflect a general principle of product liability law that applies whenever a safer alternative design is claimed.

Very recently, a Michigan federal district court dismissed a plaintiff's design defect claims involving a polyester hernia mesh device, because the plaintiff did not plead the existence of safer alternative designs. *See Barnes v. Medtronic, PLC*, 2019 WL 1353880 (E.D. Mich. Mar. 26, 2019). As safer alternatives, the plaintiff identified another surgical procedure (the Shouldice technique), a biologic mesh, and a polypropylene mesh. *Id.* at *1. Dismissing the plaintiff's design defect claims, the court found as follows:

Plaintiff's theory alleges that all polyester hernia meshes are unacceptable. Her proposed alternatives are alternative treatment methods or alternative types of mesh, not alternative production practices or designs for polyester hernia mesh. The Shouldice technique is a technique for treating hernias that does not involve any mesh. Biologic mesh is another type of mesh that can be used in hernia repairs and is made out of "bovine, porcine, or human cadaver dermis." Polypropylene mesh is a different type of synthetic mesh than polyester mesh. As with ionization smoke alarms, drugs that combine estrogen and progestin, and pedicle screws, Plaintiff's design defect claim cannot succeed by categorically challenging the safety of polyester mesh and pleading only alternative categories of products as alternative production practices. Taking Plaintiff's allegations as true, she has not alleged an alternative production practice for Defendants' product—only alternative *products*, which are insufficient as a matter of law to establish a design defect claim.

Id. at *2.

The notion that traditional surgical procedures are safer alternatives to Ethicon's devices "really takes issue with the choice of treatment made by [the patient]'s physician, not with a specific fault of" the medical device. *Theriot v. Danek Med., Inc.*, 168 F.3d 253, 255 (5th. Cir. 1999)). Notably, **Dr. Elliott fully agrees**. Dr. Elliott has acknowledged that autologous slings and the Burch procedure are not medical devices. Ex. H, 9/26/15 Dep. 23:18-20, 25:3-5, 28:22-24. According to Dr. Elliott: "[W]hen we're talking about safety and complications, it's comparing apples and oranges because there is no medical device placed in those patients that's permanent. . . . Therefore, the bar is changed for the pubovaginal and Burch So really you can't compare TVT mesh, or any mesh for that matter, and the Burch or autologous fascia for

that matter.” *Id.* at 74:2-4, 93:18-21, 103:21-22 (emphasis added); *see also id.* at 73:23-24. Thus, Dr. Elliott’s opinions about these traditional surgical procedures are not changes to the design feature or the design concept of the devices at issue; instead, his opinions would eliminate the devices in their entirety.

B. Dr. Elliott’s comparison of the TVT Devices with traditional surgical procedures is unreliable.

Another reason the Court should preclude Dr. Elliott from comparing the TVT Devices with a traditional surgical procedure is that his opinions are admittedly unreliable. Asked why his expert report did not set forth any opinion about TVT complication rates, Dr. Elliott responded that it was “[b]ecause *we don’t know* the true complication rate.” Ex. G, 9/26/15 Dep. 196:7-14; *see also id.* at 110:13-17 (emphasis added). For this reason alone, the Court should exclude Dr. Elliott’s opinions. Because Dr. Elliott admittedly does not feel qualified to testify about complication rates, he is not competent to opine that TVT Devices pose a higher risk of complications than non-mesh procedures.

Dr. Elliott’s opinions should also be excluded because, rather than relying on medical studies and other sound scientific methodology in support of his opinions as required by *Daubert*, Dr. Elliott improperly relies on a perceived *lack of data* as a basis for his opinions. According to Dr. Elliott, “[t]he data overall with all sling products is very poor,” including studies relating to autologous slings, “[a]nd that’s why we’re in the situation we’re in now.” *Id.* at 63:11-14, 75:17-76:21; 79:13-14. Dr. Elliott stated that he disagrees with the American Urological Association’s (“AUA’s”) conclusion that synthetic polypropylene mesh has minimal morbidity compared to alternatives, but the basis for his disagreement simply is his belief that “there have been very few randomized control trials, none which are long-term, comparing head-

to-head autologous pubovaginal slings versus TVT.” *Id.* at 118:19-25; *see also id.* at 123:19-24; 187:21-188:1.

Aside from the fact that Dr. Elliott has a misperception about TVT Device literature, Dr. Elliott improperly infers that this perceived lack of studies demonstrates that the AUA is wrong and that TVT is less safe than alternative surgical approaches. The essence of Dr. Elliott’s opinions is that: (a) he is not really sure whether or not TVT Devices are safer than alternative procedures; (b) Ethicon should have conducted additional testing before marketing the devices; and (c) because Ethicon did not do so, he will assume that the TVT Devices are not as safe. This approach is far from trustworthy scientific methodology.

When asked about mesh-related pain, Dr. Elliott conceded: “The true incidence, unfortunately, is not known.” Ex. H, 9/26/15 Dep. 261:1-5. He further testified:

Q. Now, I believe you said that you believe that the long-term dyspareunia rates with the TVT were higher than pubovaginal, did you say, and the Burch?

A. I don't recall if I mentioned the Burch in there. What I mentioned was the pubovaginal and the Burch have traditionally been a very common procedure done up until the mid-'90s and into probably early 2000's. And in my practice, I have never seen a woman come in with severe pain, life altering pain from either of those aforementioned procedures. But I see it commonly, weekly with the meshes, including the TVT.

Q. You can't point to any comparative trials that show a statistically significantly higher rate of dyspareunia for the TVT retropubic device compared to either the Burch or the pubovaginal sling; correct?

A. Those studies, as you've mentioned, *have not been done*.

Q. And actually, the one paper you pointed me to earlier about the Burch had the 4 percent rate of dyspareunia with that procedure long-term; correct?

A. It wasn't 4 percent. It was 3.9 percent.² . . .

² Dr. Elliott refused to state whether he felt that 3.9% was acceptable. Ex. H, 9/26/15 Dep. 67:21-68:23. This same Burch study upon which Dr. Elliott relied showed an alarming 22% rate of urgency at long term follow up, demonstrating that the procedure is much less efficacious than TVT. *Id.* at 67:4-6; Ex. N.

Q. Okay. And you can't point to any studies on TVT that show a rate higher than 3.9 percent at that length of follow-up for dyspareunia; can you?

MR. CARTMELL: Object to the form.

A. *Because that study has not been done.* As I mentioned, no studies focused specifically on output -- end point of dyspareunia have been done.

Id. at 327:13-329:2 (emphasis added).

In fact, such studies have been done, and Dr. Elliott has chosen to ignore them. For instance, Heinonen and others performed a 10-year TVT study reporting zero cases of dyspareunia at 10 years follow-up, thus demonstrating that Dr. Elliott's understanding is flat wrong. Ex. Q. Dr. Elliott could not recall whether he had reviewed that study. Ex. G, 9/26/15 Dep. at 329:11-21. Nor could Dr. Elliott reconcile his testimony with the AUA guideline and Society of Gynecological Surgeons' meta-analysis and systematic review, both of which reported higher rates of dyspareunia, pain, and sexual dysfunction with the autologous sling and Burch procedure as compared to mid-urethral mesh devices. *Id.* at 331:20-332:3; Ex. I & J. Even Dr. Elliott's own employer, the Mayo Clinic, advertises that "[u]sing surgical mesh is a safe and effective way to treat stress urinary incontinence." Ex. O.

Dr. Elliott has also arbitrarily discounted literature that he, himself, cites in his report. For instance, when asked about a Cochrane review cited in his own report, (Ex. P; Ex. C, TVT Report at 37 n. 98), Dr. Elliott testified as follow:

Q. And this Cochrane Review you cite to in your report does say that "The reported occurrence of problems with sexual intercourse including pain was low" [concerning mesh devices]; correct?

A. That's what they state, yes.

Q. And you didn't acknowledge that point in your report; did you?

A. I talk about dyspareunia in there.

Q. Did you acknowledge that the Cochrane Review that you cite to states that problems with sexual intercourse, including pain, were low in your report?

A. I don't recall using those specific words, no.

Q. Why not?

A. Because, again, this is a meta-analysis of poor quality or moderate quality studies that do not focus on dyspareunia. And specifically they're short-term studies. It does not tell -- also, these are in the hands of experts, high-volume surgeons. Does not tell us the rate of the true average surgeon out there, which is known to be much higher.

Ex. H, 9/26/15 Dep. 111:3-25. In fact, the authors of that Cochrane review upon which Dr. Elliott supposedly relied concluded: "Mid-urethral sling operations have been the most extensively researched surgical treatment for stress urinary incontinence (SUI) in women and have a good safety profile. Irrespective of the routes traversed, they are highly effective in the short and medium term, and accruing evidence demonstrates their effectiveness in the long term. This review illustrates their positive impact on improving the quality of life of women with SUI." Ex. 4, to 9/26/15 Dep. (Ex.G), at 3.

In *Winebarger v. Boston Scientific Corp.*, 2015 WL 1887222, at *8 (S.D. W. Va. Apr. 24, 2015), this Court noted that "[a]n expert's opinion may be unreliable if he fails to account for contrary scientific literature and instead "selectively [chooses] his support from the scientific landscape." (Citations omitted). Here, Dr. Elliott has achieved the conclusion that he wants to achieve by cherry-picking favorable portions of certain papers while arbitrarily rejecting unfavorable portions of those same papers. In the same manner, he has arbitrarily discounted other studies that do not comport with the opinions he would like to offer in this case. Because Dr. Elliott's failure to account for this literature is not based on any sound scientific principles, his opinions are unreliable and should be excluded.

Finally, the Court should find that Dr. Elliott's personal experiences—unsupported by any trustworthy scientific methodology—fall short of setting forth a reliable foundation for his opinions.³ In *Winebarger*, this Court found that an expert “may not solely rely on his personal observations, especially when he seeks to provide broad opinions.” 2015 WL 1887222, at *10. *See also Cisson v. C.R. Bard, Inc.*, 948 F. Supp. 2d 589, 606 (S.D. W. Va. 2013) (finding that an expert's calculation of complications rates based on his personal experiences “has no basis in any reliable methodology”). Here, Dr. Elliott seeks to offer broad opinions that are based on his personal experiences. Not only are these personal experiences uncorroborated by scientific studies, they are inconsistent with scientific studies. Accordingly, Dr. Elliott's opinions do not satisfy the rigors of *Daubert* scrutiny and should be excluded. Alternatively, the Court should reserve ruling on this issue. *See In re: Ethicon, Inc. Pelvic Repair Sys. Prod. Liab.. Litig.*, 2016 WL 4500766, at *4 (S.D. W. Va. Aug. 26, 2016).

VI. The Court should preclude Dr. Elliott from comparing TVT Secur with other medical devices.

For similar reasons, the Court should not allow Dr. Elliott to suggest that TVT, TVT-O and/or other devices were safer, feasible alternative devices to TVT Secur. In his TVT Secur general report, Dr. Elliott states that “the best course of action is to avoid using polypropylene mesh in the pelvic floor” and that “traditional surgical repairs” are a safer alternative. Ex. E, TVT Secur Report at 36. However, he also states that “TVT and TVT-O had far better success rates than the TVT-S,” thus suggesting that he intends to testify that TVT and TVT-O were safer alternatives. *Id.*

³ Dr. Elliott testified about a basic unfamiliarity with autologous sling literature and the experiences of other physicians, stating that “I can't speak to those. I can speak to my own experience.” Ex. G, 9/26/15 Dep. 315:24-25; *see also id.* at 316:21-317:18.

In response to deposition questioning, however, Dr. Elliott definitively clarified that he believes that all mid-urethral mesh slings are “unsafe.” Ex. H, 9/26/15 Dep. 143:11-14, 144:16-18. According to Dr. Elliott, “[m]esh should not be placed in the vagina,” period. *Id.* at 285:22. Quite simply, Dr. Elliott should not be permitted to suggest that other mesh products offer a safer alternative to TVT Secur given that he is unwilling to stand behind the alternative and confirm that it is safe and effective in treating SUI. Indeed, Dr. Elliott’s TVT and TVT-O general reports reveal that he unequivocally believes that those devices are unsafe. Ex. C, TVT Report; Ex. D, TVT-O Report. Dr. Elliott may not be permitted to tell one jury that TVT is unsafe, and then turn around and tell another jury that it was a suitable, safer alternative to TVT Secur.

Finally, Dr. Elliott’s opinions on this topic should also be excluded on the basis that they are unreliable for the reasons set forth in Section II.B above.

VII. The Court should preclude Dr. Elliott from testifying that a device with lighter weight, larger pore mesh would serve as a safer alternative.

Ethicon adopts its Wave 3 argument on this issue set forth in Section II.B of Doc. 2815.

VIII. The Court should preclude Dr. Elliott from criticizing the cut of TVT mesh.

Ethicon adopts its Wave 3 argument on this issue set forth in Section III of Doc. 2815.

IX. The Court should preclude Dr. Elliott from testifying about alleged mesh degradation, shrinkage, contraction, and other biomaterials opinions.

Ethicon adopts its Wave 3 argument on this issue set forth in Section V of Doc. 2815.

X. The Court should not allow other opinions beyond Dr. Elliott’s expertise and/or that are otherwise improper.

Ethicon adopts its Wave 3 argument on this issue set forth in Section VI of Doc. 2815.

CONCLUSION

For the foregoing reasons, the Court should limit Dr. Elliott’s testimony in these cases.

Respectfully submitted,

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**IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION**

IN RE: ETHICON, INC. PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	Master File No. 2:12-MD-02327 MDL No. 2327
THIS DOCUMENT RELATES TO ETHICON WAVE 10 CASES	JOSEPH R. GOODWIN U.S. DISTRICT JUDGE

CERTIFICATE OF SERVICE

I, William M. Gage, certify that on this date, I electronically filed the foregoing document with the Clerk of the Court using the CM/ECF system which will send notification of such filing to the CM/ECF participants registered to receive service in this MDL.

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